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EXHIBITS

- Y. Higuchi et al., *Biotechnology*, 10: 413–417 (1992).
- Z. Higuchi et al., *Biotechnology*, 11: 1026–1030 (1993).

Plaintiffs Life Technologies Corporation and Applied Biosystems, LLC (Life Tech) and Defendants Biosearch Technologies, Inc. and Eurofins MWG Operon Inc. (Defendants) jointly request construction of three claim terms.¹ Life Tech's constructions come from definitions in the specification, while Defendants' constructions violate key claim construction principles by reading in additional limitations and excluding preferred embodiments. The parties differ on whether five other terms need construction. Defendants have not identified a concrete dispute to which their constructions relate, nor why the constructions aid in understanding the claims. Defendants' constructions also contradict the law and the intrinsic record. The Court should therefore adopt Life Tech's three proposed constructions and decline to construe the remainder.

I. LIFE TECH'S CONSTRUCTIONS HONOR THE PATENTS' DEFINITIONS

Defendants do not dispute that Life Tech's constructions are based on definitions in the specification and that when such a definition is clear, the inventor's lexicography governs. *See e.g.* Life Tech Br. (D.I. 180) at 8; Defendants Br. (D.I. 192) at 2-3. The inquiry should end there, with the application of a fundamental principle to undisputed facts.

A. "quencher molecule"

The dispute is essentially whether this term should be construed as it is expressly defined in the specification, or instead further limited to only those quenchers that are fluorescent (i.e., able to emit light at a different wavelength from the one absorbed).

1. "Quencher Molecules" Can Be Either Fluorescent or Non-Fluorescent

Defendants candidly admit "the specification for the Patents-in-Suit discloses quenchers that emit light and quenchers that do not emit light," and do not dispute that Life Tech's proposed construction comes verbatim from the definition provided in the specification.

¹ The asserted patents are U.S. Pat. Nos. 5,538,848 (Ex. A); 5,723,591 (Ex. B); 5,876,930 (Ex. C); 6,030,787 (Ex. D); and 6,258,569 (Ex. E) (the Livak Patents). Exhibits A-X refer to exhibits attached to Life Tech's Opening Claim Construction Brief (D.I. 180). Exhibits Y-Z refer to exhibits attached to this brief.

Compare Life Tech Br. at 11 *with* Defendants Br. at 6. They also admit that where the patentees intended to further limit the claims to quenchers that are fluorescent, they knew how to do so. Defendants Br. at 7 (“amending the claim to recite that the quencher molecule is fluorescent”).

2. Courts Cannot Rewrite Claims to Save Them from Invalidity

Confronted with a clear definition of “quencher molecule” that includes non-fluorescent quenchers, Defendants construct an elaborate hypothetical in which some claims would supposedly be rendered either nonsensical, invalid, or meaningless if they were applied to non-fluorescent quenchers.² Defendants then urge the Court to rescue those few claims from that fate by rewriting all of the claims to exclude non-fluorescent quenchers. *Id.* at 4-7. But:

Chef America Inc. v. Lamb Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004), among other cases, ***prohibits*** courts from rewriting claims instead of interpreting the claims as written. In *Chef America*, the court refused to redraft the claims to replace the term “to” with the term “at,” even though that refusal produced a nonsensical result. *Id.*

Wellman, Inc. v. Eastman Chem. Co., No. 2010-1249, 2011 U.S. App. LEXIS 8903 at *30 (Fed. Cir. Apr. 29, 2011).³ Defendants’ argument that claims should be rewritten is flawed.

Defendants misapply the principle that “[c]laims amenable to more than one construction should, when it is reasonably possible to do so, be construed to preserve their validity.” Defendants Br. at 6. The claims here are ***not*** “amenable to more than one construction,” as shown above. The time for Defendants to challenge validity is later,⁴ not now; the Federal Circuit has “not endorsed a regime in which validity analysis is a regular component of claim construction.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005).

² This scenario is hypothetical in part as Defendants have not shown that the quenchers in their accused products are non-fluorescent, although presumably they will attempt to do so if their proposed construction is adopted.

³ Unless otherwise noted, all emphasis in quotations is added.

⁴ At this stage Defendants allege that claims such as claim 16 of the ’930 patent would be “nonsensical.” Defendants Br. at 5. But this claim recites that the quencher molecule is fluorescent, Ex. C at col. 24, ll. 62-63; in other words, Defendants’ premise that “quencher molecule” must be rewritten everywhere it appears in order to rescue claim 16 of the ’930 patent from a nonsensical result is false on its face.

3. Life Tech Is Amenable to Making the Construction More Accessible

Finally, Defendants quibble with the express definition in the specification by crudely substituting the term “quencher molecule” with its definition to create an awkward and arguably partially redundant phrase. Defendants Br. at 8-9. This misses the point of the dispute. Life Tech does not object to refining the construction for better jury comprehension, if necessary.

B. “a hairpin structure”

The dispute is again whether to construe the term as the patentees expressly defined it in the specification, or to omit that definition’s requirement that “the quencher molecule is brought into proximity with the reporter molecule.” Ex. B, col. 1, ll. 49-51.

1. “A Hairpin Structure” Brings the Quencher Next to the Reporter

The parties agree that a probe must hybridize to itself in order to form a hairpin structure. Defendants Br. at 9. They also agree that more is required, they only differ on exactly what that is. Following the express definition in the specification and other intrinsic evidence, Life Tech’s construction further requires that “the quencher molecule is brought into proximity with the reporter molecule.”⁵ Life Tech Br. at 13.⁶ Defendants do not dispute that Life Tech’s construction is taken from an express definition, nor that a patentee’s “lexicography governs.” *Phillips*, 415 F.3d at 1316. As with “quencher molecule,” above, that should end the inquiry.

Confronted with this express definition, the most that Defendants can muster in response is that it makes other claim limitations redundant,⁷ and that “the term ‘hairpin structure,’ taken

⁵ Life Tech’s construction clarifies the meaning of the word “proximity” as “next to” based on the prosecution history in order to “provide meaning to a lay juror.” Life Tech Br. at 13-14.

⁶ Following the patentees’ express definition, Life Tech’s construction also requires “form[ing] a loop” and “the absence of a complementary nucleic acid sequence to prevent the formation of the hairpin structure.” Defendants make no argument against including these requirements. Defendants Br. 9-14.

⁷ The other claim terms do not specify that the hairpin structure brings the quencher and reporter into proximity, which is the crux of the dispute. If Defendants are willing to stipulate that they do, then Life Tech is amenable to an alternative construction that avoids the alleged redundancy.

alone, does not speak to reporters or quenchers, nor does it speak to their relative proximity.” Defendants Br. at 13. But “hairpin structure” is not “taken alone” and divorced from the rest of the patent. It consistently appears in the specification, claims, and prosecution history in the context of reporters and quenchers and their relative proximity, specifically to distinguish prior art in which a hairpin structure brought a quencher and reporter next to each other. Life Tech Br. at 13.⁸

2. Defendants’ Stretch to Add Other Requirements for “A Hairpin Structure” Is at Best Inconsistent

While Defendants object to including the requirement regarding hairpin structures taken verbatim from the specification, they add two others: (1) “3 or more contiguous basepairs” and (2) “at the detection temperature of the assay,” which are not taken verbatim from the specification.⁹ Rather, they are merely inferred from, respectively, (1) a figure in a prior art reference cited in the specification, and (2) “basic science,” other limitations in one claim of one patent, a Notice of Allowability for one patent, and attorney argument. Defendants Br. at 10-12.

Defendants cannot have it both ways. They cannot simultaneously stretch to include additional requirements based on inferences from scattered sources while excluding a

⁸ Despite Defendants’ protests that Biosearch’s own patents—which use the identical definition of hairpin structure—are irrelevant, they do rebut Defendants’ argument that in the relevant field the term “hairpin structure” is not used in the context of reporters, quenchers, and their relative proximity, but instead “relates solely to the structure of the oligonucleotide strand.” Defendants Br. at 12-13. As rebuttal, this extrinsic evidence may be considered. Nor do Defendants argue they lacked sufficient notice to respond to any evidence cited in Life Tech’s brief.

⁹ While Life Tech is skeptical that the Defendants’ proposal to include these additional requirements in the construction comports with proper claim construction methodology, it has no other objection to including them, provided “3 or more contiguous basepairs” is understood to be a necessary but not sufficient requirement. Otherwise, Defendants’ construction would exclude a preferred embodiment. Specifically, Defendants do not deny that the disclosed P2 probe is a preferred embodiment and they admit that it “is obviously within the scope of ‘3 or more contiguous base pairs [sic].’” Defendants Br. at 12. However, “a hairpin structure” is used in the claims and intrinsic record as a “negative limitation” to explicitly *exclude* probes that form such a structure. *See, e.g.*, Ex. B, ‘591 patent, Claim 1 (“[A]n oligonucleotide sequence which *does not* hybridize with itself to form a hairpin structure....”); Life Tech Br. at 14-16. In other words, if “3 or more contiguous base pairs” were a sufficient and not merely necessary requirement to meet the “hairpin” limitation, then because “hairpin” is a negative limitation, the preferred embodiment P2 would be excluded. Such a construction is “rarely, if ever, correct,” and must be established with “highly persuasive evidentiary support.” Life Tech Br. at 8.

requirement from an express definition in the specification.

C. “said reporter/quencher molecule is separated from said quencher/reporter molecule by at least 15 nucleotides”

The parties agree that the specification passage “[a] separation of about 6-16 nucleotides ... is typically achieved by attaching one member of a reporter-quencher pair to the 5’ end of the probe and the other member to a base 6-16 nucleotides away” gives direction for the proper construction of the claim term “separated from.” *Id.* at 15-16. The dispute is over “[w]hat is the ‘away’ in reference to?” *Id.* at 16. The answer is given by the phrase itself: “the 5’ end of the probe.” As the Livak patents refer repeatedly to the 5’ end of the probes as the “5’ terminal nucleotide,” this means the other member is 6-16 nucleotides away from the “5’ terminal nucleotide.” *See* Ex. A, claim 9. This phrase, which comes verbatim from the specification, provides the patentees’ definition of “separation,” or “separated from.” *See Bell Atl. Network Servs., Inc. v. Covad Commc’ns Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) (“[A] claim term may be clearly redefined without an explicit statement of redefinition.”).

Defendants point to other language in the specification that does not concern “separation”; it instead concerns probe naming and nucleotide position conventions. Defendants Br. at 15.¹⁰ Neither convention is at issue in the instant dispute – “separation” is. Thus, that language cannot alter the specification’s definition of “separation,” discussed above. Life Tech’s proposed construction is consistent with the intrinsic record, and should be adopted.

II. BIOSEARCH HAS NOT JUSTIFIED CONSTRUING “TERMINAL NUCLEOTIDE” AND “MONITORING THE FLUORESCENCE”

It is long past time for Defendants to “put up or shut up” about why “terminal nucleotide”

¹⁰ Defendants make no effort to reconcile the contradiction between their construction and the way the term is used in the prosecution history. *See* Life Tech Br. at 18-19; Defendants Br. at 14-16. And, while Defendants argue that “[t]here is no reason why the nucleotide attached to the first member of the reporter-quencher pair would not be counted,” Defendants Br. at 16, the law does not require an explanation for lexicography, *see Philips*, 415 F.3d at 1316.

and “monitoring the fluorescence” need construction. The Court should not devote resources to the issuance of advisory claim construction opinions where the parties do not have a concrete dispute regarding infringement or invalidity.¹¹ *See, e.g., Semiconductor Energy Lab Co. v. Samsung Elecs. Co.*, No. 09-CV-01, 2009 WL 3731959, *1 (W.D. Wis. Nov. 4, 2009). Likewise, the Court should decline to construe terms where “[t]he plain meaning of the term is sufficiently clear and the patentee never clearly and unambiguously adopted a different construction during prosecution.” *Northeastern Univ. v. Google, Inc.*, No. 2:07-CV-486, 2010 WL 4511010, *12–14 (E.D. Tex. Nov. 9, 2010). Defendants refuse to explain why a judicial construction of these terms would be anything other than an advisory opinion, or in what way the terms are ambiguous or were given a special definition by the patentees during prosecution.¹²

A. “terminal nucleotide”

Defendants do not give any reason to construe “terminal nucleotide.” The Court should thus decline to construe this term.

B. “monitoring the fluorescence”

Assuming “monitoring the fluorescence” should even be construed, the parties dispute whether it should be further limited to monitoring fluorescence only at the conclusion of an amplification reaction.¹³ Strikingly, Defendants concede that the words “monitoring” and “fluorescence” themselves do not need further construction, as they use them without substitution in their construction. Defendants Br. at 17 (“*monitoring* the generation of

¹¹ Defendants unashamedly hide the ball and only vaguely assert that construction of these claims relates to their defenses with no statement of what those defenses are, let alone how they relate. Defendants Br. at 17 n. 5.

¹² Even assuming “terminal nucleotide” and “monitoring the fluorescence” should be construed, Defendants did not respond to Life Tech’s identification of their plain and ordinary meanings as evidenced by their use in the intrinsic record as “the end monomer of an oligonucleotide,” and “checking on the fluorescence during the reaction,” respectively. *See* Life Tech Br. at 20 n. 4 and 21 n.5.

¹³ While Defendants’ proposed construction also limits monitoring to a single wavelength, they do not respond to Life Tech’s critiques of this position, and so they have waived this further limitation. *See* Defendants Br. at 17-21.

fluorescence at a particular wavelength only at the conclusion of an amplification reaction”). Defendants seek merely to import limitations from the specification and from extrinsic references, and not to provide guidance to the jury on what these words mean.

1. Intrinsic Evidence Shows “Monitoring” During Reactions

Defendants argue that monitoring “only at the conclusion of an amplification reaction ... accurately reflects what ‘monitoring the fluorescence’ was understood to mean at the time of the filing of the Patents-in-Suit.” Defendants Br. at 17-21. But the intrinsic record shows that this is not true. Rather, the record expressly shows “monitoring” *during* reactions.

The patents-in-suit cite 1992 and 1993 publications disclosing monitoring fluorescence *during* reactions in “real time.”¹⁴ Ex. A at col. 1, ll. 37-38. For example, the 1992 article teaches “continuous *monitoring*” of fluorescence during reactions by “using a fiber optic device ... to direct excitation illumination from a spectrofluorometer to a PCR *undergoing* thermocycling and to return its *fluorescence*” for measurement. Ex. Y at 415. The 1993 article discloses “[c]ontinuous *monitoring* using a video camera” to “capture *fluorescence* images of an array of PCRs.” Ex. Z at 1026. These two references show that a skilled artisan, reading the intrinsic record, would understand “monitoring the fluorescence” to refer to checking on the fluorescence as the reaction progressed using either of two “home-made” systems for doing so.

Defendants assert it was “reality that ‘real time’ monitoring of PCR *using dual-labeled probes* was not publicly available at the time of the invention.” Defendants Br. at 17.¹⁵ While this sentence recognizes the important role that the Livak Patents played in developing dual-

¹⁴ Higuchi et al., *Biotechnology*, 10: 413–417 (1992), Ex. Y, and Higuchi et al., *Biotechnology*, 11: 1026–1030 (1993), Ex. Z.

¹⁵ Defendants contend “[t]he specification of the Patents-in-Suit shows that the inventors desired real time analysis for PCR using dual-labeled probes, but that it was not a reality at the time the ’848 patent application was filed.” Defendants Br. at 20. However, the only support is a section about “the design of instruments,” *id.* (citing Ex. A at col. 1, ll. 33-42), and immediately following this section the two references discussed above – which monitored the fluorescence in “real time,” albeit with “home-made” equipment rather than a commercial instrument – are cited.

labeled probes for real-time reactions, it says nothing about term “monitoring the fluorescence.” As discussed above, skilled artisans reading the intrinsic record would have been familiar with monitoring fluorescence during DNA reactions and would have known that those words meant.

2. Defendants’ Misread the Extrinsic Evidence

Defendants argue that extrinsic publications show that inventor Dr. Livak “did not consider real time PCR monitoring to be within the scope of the original invention because he came up with it only after having access to the ABI Prism machine.” *Id.* at 20. The cited references do not give rise to such an inference, let alone state this directly.

Rather, the first article cited by Defendants explains that “[r]esearchers have developed several methods of quantitative PCR and RT-PCR,” and describes different methods that measure product during PCR reactions. Defendants Br., Ex. C at 986. This article states that its “goal was to develop a *high-throughput*” methodology for such real time measurements. *Id.* at 987. Indeed, it discloses a machine that allows “high-throughput” measurement for 96 samples simultaneously. *Id.* The mere fact that, as Defendants note, the paper discloses “*a* novel ‘real time’ quantitative PCR method ... resulting in much faster and higher throughput assays,” does not mean that there were no other real time quantitative PCR methods already in existence. Defendants Br. at 19. And from the intrinsic record we know that there were.

Nor does language in marketing collateral that a particular instrument “introduced the world to real-time PCR” mean that those of skill in the art did not already know how to monitor fluorescence from DNA reactions as they progressed. Defendants Br., Ex. D. Rather, marketing language that an instrument introduced a technique “to the world,” could mean that the instrument made a technique known outside of those skilled in the art or that it made the technique easy or affordable. The Higuchi references show that even before commercial machines were available, a researcher could make a “home-made” apparatus to measure

fluorescence in reactions in real time. The extrinsic evidence cited by Biosearch does not show that those of skill in the art would not have understood that “monitoring the fluorescence” meant checking on the fluorescence as a reaction progressed at the time the ’848 patent was filed.

III. DEFENDANTS’ THREE LENGTHY TERMS ARE NOT IN MEANS-PLUS-FUNCTION FORMAT AND NO CONSTRUCTION IS REQUIRED.

The last three “terms” in dispute are long phrases which are not in “means-plus-function” format governed by 35 U.S.C. § 112, ¶ 6, are not indefinite, and do not require construction.

A. The Strong Presumption Against § 112, ¶ 6 Has Not Been Overcome

Where a claim lacks the word “means,” the Federal Circuit has emphasized that “the presumption [that the claim is not governed by § 112, ¶ 6] flowing from the absence of the term ‘means’ is a strong one that is not readily overcome.” *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004).

Defendants have not overcome this strong presumption. Instead, they admit these terms recite “an oligonucleotide sequence or probe,” a structure that performs the alleged functions. Defendants Br. at 23. While this admission is fatal to their position,¹⁶ Defendants nevertheless make two arguments. First, they point to recited properties of the oligonucleotide, and dub these properties “function.” *Id.* at 23, 25, 29. Yet Biosearch’s own authority recognizes that recitation of a structure’s operation makes it less likely that the term is governed by § 112, ¶ 6, not more.¹⁷ Defendants have not shown that one of skill in the art would not have understood the structural arrangements of the probe, and so they have not met their high burden.

¹⁶ “Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function.” *Phillips*, 415 F.3d at 1311; *see also* Life Tech Br. At 9-10.

¹⁷ In *Power Integrations* the court held that the term “soft start circuit” was in means-plus-function format only because it differed from cases where “the term ‘circuit’ was sufficiently coupled with a description of the circuit’s operation such that ‘persons of ordinary skill in the art would understand the structural arrangement of the circuit components from the term ‘circuit’ *coupled with the qualifying language of the claim 1*” *Power Integrations v. Fairchild Semiconductor Int’l, Inc.*, 422 F. Supp. 2d 446, 460 (D. Del. 2006) (emphasis in original); *see also* *Massachusetts Inst. of Tech. and Elec. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1355 (Fed. Cir. 2006).

Second, Defendants argue – without citing any legal authority – that because there are many possible sequences for a nucleotide probe, “[a] person of ordinary skill in the art reading the claim would not be able to identify what the sequences are for performing the recited function.” Defendants Br. at 23-24. But such an argument has already been rejected by this Court and the Federal Circuit. Indeed, “[t]he fact that [a] term [i]s broad and might include almost an infinite number of structures d[oes] not render the limitation subject to § 112, ¶ 6.”¹⁸ *Crane Co. v. Sandenvendo Am.*, No. 07-CV-42-CE, 2009 U.S. Dist. LEXIS 47509, at *40-41, 43 (E.D. Tex. June 5, 2009); *see also Lighting World*, 382 F.3d at 1361-62.

B. These Terms Are Not Indefinite and Do Not Require Construction

In the alternative, Defendants argue the second two terms are indefinite “because fluorescence intensities vary widely with different conditions.” Defendants Br. at 26, 30. Yet as Life Tech described in its opening brief, “optimization of oligonucleotide hybridization conditions were routine and well known in the art at the time of that patent.” Life Tech Br. at 27. Defendants’ efforts to show how conditions such as magnesium concentration impact reactions only reaffirms that skilled artisans know how to optimize such reactions. *See* Defendants Br. at 26-27. Thus, these terms are not indefinite.

Finally, Defendants give a second, alternative construction for these terms. *Id.* at 27, 30. However, they do not address, let alone rebut, Life Tech’s explanation of why this construction is improper. *Compare* Life Tech Br. at 30 *with* Defendants Br. at 27, 30.

IV. CONCLUSION

Life Tech respectfully requests that the Court adopt Life Tech’s three proposed constructions and decline to construe the remaining five terms.

¹⁸ Thus, Defendants’ assertion that “[p]robe” ... does not denote any structure,” fails. Defendants’ Br. at 23 n.7.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 5th day of August, 2011.

/s/ Cora Louise Schmid